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| 09/869,777      | 09/21/2001  | Suzanne V. Smith     | 11184.00002         | 8748             |

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EXAMINER

HARTLEY, MICHAEL G

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/869,777

Applicant(s)

SMITH ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3, 30-38 and 49-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 30-34, 49-57 and 62-75 is/are allowed.
- 6) ☒ Claim(s) 35-38, 58-61, 76 and 77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/16/2004 has been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-38, 58-61, 76 and 77 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of imaging and method of radiotherapy for cancer using radionuclide complexes, does not reasonably provide enablement for generically "diagnosis" or "diagnosis of disease" or "therapy" or "therapy of a disease". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

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The invention provides chelating compounds that may complex with various metals for methods of imaging, i.e., radioimaging (throughout specification) and MRI imaging (page 15 of specification). The compounds are also stated as being useful for diagnosis or therapy, generically. However, the only use of the compounds which is enabled by the specification is for radiotherapy of cancer using radionuclide complexes of compounds or for methods of imaging and diagnosing tumors and the like, but not for any diagnosis of any disease.

(2) The state of the prior art

The state of the prior art is clear that no set of compounds can be used generically for "diagnosis" or "therapy" as there is no known compound that can provide diagnosis or therapy for each and every disease or condition in which diagnosis or therapy is required due to the diverse biological nature of such diseases. While radiolabeled compounds are known to be useful for radiotherapy of various cancers, the present claim recite "therapy" and "therapy of disease" which is generic to any disease.

(3) The relative skill of those in the art

The relative skill of the those in the art would not enable the "therapy" of any unidentified disease or condition by the use of a compound that only described function is to bind a metal and to be functionalized to bind a molecular recognition unit (e.g., a targeting moiety). Also, while imaging methods are known, there is no known method to diagnose each and every disease using such imaging modalities, e.g., diabetes, AIDS, etc. are not known to be diagnosable via such imaging methods.

(4) The predictability or unpredictability of the art

The unpredictability of providing therapy for a specific disease or condition is very high using compounds specifically designed to be useful for the said disease, let alone, any for of "therapy" using a compound that binds a metal. Also, there is great unpredictability in obtaining a diagnosis of various conditions by imaging alone, e.g., bacterial infections, etc., which usually require an in vitro test.

(5) The breadth of the claims

The claims are very broad. By the recitation of "diagnosis" or "therapy" and "therapy of disease" any possible disease is encompassed thereby.

(6) The amount of direction or guidance presented

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The specification provides guidance in using radiolabeled forms of the compounds in radiotherapy of cancer, see page 11. However, there is no guidance on how the compounds can be used in methods of therapy when they do not contain a radionuclide. Also, there is no guidance on how the compounds can be used to treat other diseases or conditions. There is no guidance on how to adjust dosages to obtain treatment of diverse diseases or suggested mechanisms on how the compounds can provide any "therapy" other than radiotherapy. "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. Also, while the compounds may be used in imaging modalities, such as, radioimaging and MRI, there is no guidance on how they can be used to generically diagnose any disease, but only cancer/tumors that are detectable by such imaging.

The dependent claims fall therewith.

**NOTE:** First it is suggested that the "diagnosis" or "therapy" are separated from a single claim, i.e., presenting separate claims for each. It is further suggested that the "diagnosis" claims are changed to "A method of imaging comprising administering to a subject a metal complex..." (and/or "A method of diagnosing cancer comprising administering..." and the "therapy" claims are changed to "A method of radiotherapy of cancer comprising administering a radiometal complex..." to obviate the above rejection. ALSO, see related NOTE below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-38, 58-61, 76 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are confusing because they contain two distinct methods in a single claim, i.e., a method of "diagnosis" and "therapy" which would require different steps, particulars (dosages), etc. For example, diagnosis would require an imaging step or the like, while therapy would not be expected to require such a step. It is suggested that these two different methods are separated into claims drawn to only a single method, one for imaging and one or radiotherapy of cancer, as suggested in the NOTE above.

Claims 35-38, 58-61, 76 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the required steps to make a diagnosis. For example, a diagnosis cannot be made only by the administration of a compound. Some type of information must be gleaned from the administration of the compound for the practitioner to be able to make a diagnosis (e.g., an image etc.). No information is gleaned or readily understood thereby due to the various information which may be used to make a diagnosis. Thus, essential steps are missing.

The dependent claims fall therewith.

**NOTE:** This rejection may be obviated by changing the claims to imaging claims, such as, 62, 66, 72 and 73, which have a step of performing an imaging scan to be understood therein, as they are methods of imaging, (radioimaging or MRI, as they are imaging claims). It is suggested to further clarify that these claims be separated into each imaging modality, such as, "A method of MRI imaging comprising administering to a subject an effective amount of a metal complex..." and "A method of radioimaging comprising administering to a subject an effective amount of a radiometal complex...". The recitation of "A method of MRI" or "radioimaging" in the preamble of these claims will bring into the claim that an imaging scan (i.e., MRI scan or radioimaging scan) is being performed, thereby providing all the essential steps.

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**Conclusion**

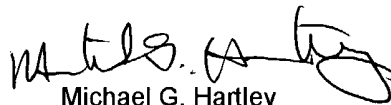
**Allowable Subject Matter**

Claims 3, 30-34, 49-57 and 62-75 are allowed as the prior art fails to teach or suggest the compounds of formula I, specifically the prior art fails to teach or suggest the inclusion of at least one of the Z group therein, as set forth in claim 3, in cryptate compounds as claimed. The methods claims can be placed in condition for allowance by following the suggestions to obviate the rejections, as set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael G. Hartley  
Primary Examiner  
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4/30/2004